

# VACCINE ADVISORY

From the Texas Department of State Health Services Immunization Branch

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*The goal of the Vaccine Advisory is to disseminate, in a timely manner, practical information related to vaccines, vaccine-preventable diseases, and the vaccine programs managed by the Immunization Branch. The Immunization Branch welcomes readers' input to improve the contents of this document.*

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**February 2, 2009**

## **Advisory No. 10. Pentacel® - [The combined Diphtheria and Tetanus Toxoids, Acellular Pertussis Adsorbed, Inactivated Poliovirus and *Haemophilus influenzae* type b Conjugate (Tetanus Toxoid Conjugate) Vaccine] (DTaP-IPV-Hib)**

This advisory presents the Advisory Committee on Immunization Practices (ACIP) recommendations on the use of Pentacel® vaccine licensed in June 20, 2008 by the U.S. Food and Drug Administration (FDA). Pentacel® is a combination vaccine that contains DTaP, IPV, and Hib [Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus, and *Haemophilus influenzae* type b Conjugate (Tetanus Toxoid Conjugate) vaccine]. The final recommendations can be found at  
[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5739a5.htm?s\\_cid=mm5739a5\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5739a5.htm?s_cid=mm5739a5_e).

### **This advisory contains:**

1. Background information
2. Summary of ACIP's recommendations and guidance for the use of Pentacel® vaccine
3. Texas Vaccines for Children Program information on Pentacel® vaccine availability for eligible participants
4. ImmTrac readiness to receive data
5. Texas school and day care facilities requirements
6. Reporting vaccine adverse events
7. Resources

## 1) Background information

Pentacel<sup>®</sup> vaccine, manufactured by Sanofi Pasteur, was licensed by the U.S. Food and Drug Administration (FDA) on June 20, 2008 for active immunization against diphtheria, tetanus, pertussis, poliomyelitis, and invasive disease due to *Haemophilus influenzae* type b (Hib).

On June 26, 2008, the ACIP voted to recommend that the newly licensed combination vaccine, Pentacel<sup>®</sup>, (DTaP-IPV-Hib), be routinely given to children at 2, 4, 6, and 15-18 months of age.

The U.S. is currently experiencing a shortage of Hib vaccine. The availability of Pentacel<sup>®</sup> will improve the Hib vaccine supply situation in the United States. However, the availability of Pentacel<sup>®</sup> is not sufficient to reinstate the last (booster) dose of Hib vaccine series (i.e., the dose administered after the first birthday). Although Pentacel<sup>®</sup> is licensed by FDA for the fourth dose in the DTaP, IPV, and Hib series, providers should not use it for the fourth dose until there is further improvement in the Hib vaccine supply (anticipated for the last quarter of 2008). Until the Hib supply improves, Pentacel<sup>®</sup> should be used ONLY for the first three doses of the DTaP, IPV, and Hib vaccination series, except as noted below.

## 2) Summary of ACIP's recommendations and guidance for the use of Pentacel<sup>®</sup> vaccine

As with all combination vaccines, there are no special rules for the use of Pentacel<sup>®</sup>, except as determined by FDA licensure of the product (i.e., the maximum age for any dose). The schedule, minimum intervals, and minimum ages are determined by the individual components. The recommended schedule for Pentacel<sup>®</sup> is similar to those for DTaP and ActHib, with doses at 2, 4, 6, and 15 through 18 months of age.

Pentacel<sup>®</sup> can be administered to any child 6 weeks through 4 years of age, without a contraindication to any component, for whom DTaP, IPV, and Hib vaccines are indicated. As stated on the childhood immunization schedule, a combination vaccine, including Pentacel<sup>®</sup>, may be used whenever any component(s) of the combination is indicated and no other component of the vaccine is contraindicated. This means that Pentacel<sup>®</sup> can be used when a child needs one or two components, but does not need the others.

Contraindications and precautions for Pentacel<sup>®</sup> are the same as those of DTaP, IPV, and Hib vaccines.

The table below provides minimum ages and intervals for the component vaccines as defined in various ACIP statements, and in particular in Table 1 of the 2006 version of the *General Recommendations on Immunization* (<http://cdc.gov.mmwr/PDF/rr/rr5515.pdf,page3>) and on page 31-32 of the 2006 AAP *Red Book*.

Parameter	Age/interval
Minimum age for any dose	6 weeks
Minimum interval for doses 1 and 2	4 weeks
Minimum age for dose 2	10 weeks

Minimum interval for doses 2 and 3	4 weeks
Minimum age for dose 3	14 weeks
Minimum interval for dose 3 and 4	6 months (determined by DTaP component; minimum interval for dose 3-4 is two months for Hib and four weeks for IPV)
Minimum age for dose 4	12 months (determined by DTaP and Hib components). Note that both the minimum interval AND age must be met for the fourth dose of DTaP or Hib (as Pentacel® or any other formulation) to be counted as valid
Maximum age for any dose	4 years, 364 days (i.e., do not administer at age 5 years or older)

Examples and guidance on schedules for Pentacel®, Pediarix®, and the single antigen series for HepB, Hib, IPV, and DTaP for healthy children\* during the Hib vaccine shortage can be found at <http://www.cdc.gov/vaccines/pubs/pentacel-guidance.htm>.

\*When supplies are sufficient an additional dose of Hib vaccine (single antigen or as part of a combination vaccine) is recommended for healthy children at 12 through 15 months of age (at least 2 months after the prior dose). Either Pentacel® or single antigen Hib vaccine may be used at 12 through 15 months of age for children who are at increased risk of Hib disease or who have not completed the Hib series. If Pentacel® is administered at 12 through 15 months of age a dose of DTaP at 15 through 18 months of age is not needed. See *MMWR* 2007;56(No.50):1318-1320 for additional details.

### 3) Texas Vaccines for Children program

Pentacel® is now available through the Texas Vaccines for Children (TVFC) Program and is approved for administration as a four-dose series at 2, 4, 6, and 15-18 months of age. However, the nation continues to be in a *Haemophilus Influenzae* type b vaccine (Hib) shortage and providers should continue to defer the fourth dose of Hib to all children whether that dose is in the form of Pentacel® or another monovalent vaccine. The quantity of Pentacel® is not sufficient to reinstate the fourth Hib dose. Until the Hib supply improves, Pentacel® should be used only for the first three doses of DTAP, IPV, and Hib vaccination series.

For more information please contact your Health Service Region, local health department, or TVFC consultant.

#### 4) ImmTrac

ImmTrac users can report Pentacel®, using the ImmTrac code “DTaPHibIPV”. Although ImmTrac can record Pentacel® vaccine doses administered, and doses will be reflected on the client immunization history, the ImmTrac immunization scheduler will not generate recommendations for Pentacel® vaccine at this time. Providers should consult ACIP recommendations to determine when the Pentacel® vaccine should be administered. For more information about ImmTrac, go to [www.ImmTrac.com](http://www.ImmTrac.com).

#### 5) Texas school and child-care facilities requirements

Pentacel® vaccine can be given to infants and children at 2, 4, 6, and 15-18 months of age.

The Immunization requirements for school and child-care facilities remain the same and can be viewed at <http://www.dshs.state.tx.us/immunize/school/default.shtm#infoforschoolchildcare>.

#### 6) Reporting adverse vaccine events

Clinically significant adverse events following vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).

Adverse events from privately purchased vaccine may be reported directly to VAERS at <http://vaers.hhs.gov/>. Secure web-based reporting is available on the VAERS website. Contact 800-VAC-RXNS (800-822-7967) for forms and information.

In Texas, reports of events following vaccination at public health clinics or with vaccine provided through public funding such as the Texas Vaccines for Children (TVFC) program should be reported through the Texas Department of State Health Services, Immunization Branch, MC 1946, P.O. Box 149347, Austin, TX 78714-9347. The pre-addressed and postage-paid VAERS form with this address can be obtained by calling the Immunization Branch. A copy of the form is also available in the TVFC toolkit. To request a VAERS form or additional information, call the VAERS contact in your area:

- **In Texas:** (800) 252-9152
- **For Bexar County:** (210) 207-2087
- **For City of Houston:** (713) 558-3518

#### 7) Additional resources

##### For providers (Vaccine):

- Prescribing information for the Pentacel® vaccine: <http://www.pentacel.com>
- CDC Pentacel® guidance on the use of the vaccine webpage: <http://www.cdc.gov/vaccines/pubs/pentacel-guidance.htm>
- Pentacel® package insert (pdf file): <http://www.fda.gov/cber/label/pentacelLB.pdf>

For public (Diseases):

- Diphtheria: <http://www.cdc.gov/vaccines/vpd-vac/diphtheria/default.htm>
- Pertussis: <http://www.cdc.gov/vaccines/vpd-vac/pertussis/default.htm>
- Tetanus: <http://www.cdc.gov/vaccines/vpd-vac/tetanus/default.htm>
- Polio: <http://www.cdc.gov/vaccines/vpd-vac/tetanus/default.htm>
- Hib: <http://www.cdc.gov/vaccines/vpd-vac/hib/default.htm>

*We hope you generously forward this advisory to others who may benefit from this information.*

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P.O. Box 149347, Austin, Texas 78714-9347. (512) 458-7284 or (800) 252-9152  
[www.ImmunizeTexas.com](http://www.ImmunizeTexas.com)

